REMARKS

Claims 48-60 and 64-68 are pending in the Application. Claims 48, 52, and 66 have been amended. In the Response to Arguments section of the Office Action, the Examiner deemed the amendments and arguments filed in the Request for Continued Examination (RCE) as not persuasive. In particular, with respect to Applicants' argument that the primary Margulies et al. prior art reference fails to disclose a sealing member that is configured such that injected sealing material will perfuse via the transverse opening(s) *but not the longitudinal opening depending on the location of the sealing member relative to the cannula*, the position is taken in the current Office Action that reference number (40) (injection tube) in Margulies et al. is considered the sealing member.

The Office Action also concludes that the method employed by Margulies et al. discloses the claimed feature of moving the sealing member from a first position to a second position, wherein in the second position the implant material is substantially prevented from exiting the cannula body via the longitudinal opening (e.g., distal). Specifically, the Office Action states:

> "As cement is placed into the distal end of the cannula (column 5, lines 40-61), the cement will perfuse through the holes of the cannula and into the surrounding tissue where it will fill the surrounding area. The device is then pulled in a proximal direction (column 5, lines 40-61) in order to fill the proximal portions with cement. Since the device is initially placed in the distal portion of the cannula, this portion will be filled first and once cement is in place there the remaining cement will be substantially prevented from exiting the longitudinal hole at the distal end." Office Action, page 7.

Applicants respectfully disagree with the above-noted assessment regarding Margulies et al. and request reconsideration in light of the amendments and remarks made herein.

§ 102(e) Rejection

Claims 48-54, 56-58, 60, 64, 65, and 66 stand rejected as being anticipated under § 102(e) as being anticipated by Margulies et al. The Margulies et al. prior art reference discloses a method and device for the augmentation of the femoral neck. A hole is first drilled into the femoral neck and the hole is filled with uncured cement. An open-ended tube (i.e., implant) having openings at the ends and through its wall is then inserted into the hole and attached to the bone. An injection tube is provided to inject cement into the surrounding cancellous bone. The injection tube is described as being dimensioned (i.e., outer diameter) to provide a tight but sliding fit within the implant. Col. 4, lines 55-58. The space between the outer dimensions of the injection tube and the internal surface of the implant are large enough such that air escapes during cement injection but small enough such that cement does not flow backward through this annular space. Col. 6, lines 4-13. The only sealing aspect disclosed in Marguilies et al. relates to the tight, sliding fit between the exterior surface of the injection tube and the inner surface of the implant – there is no separate sealing member.

In particular, Applicants have amended independent claims 48 and 66 to even more distinctly claim the feature that the sealing aspect resides on a plunger. In particular, a separate pliable sealing member is disposed on the plunger. The pliable sealing member (134) is such that, in an uncompressed state, it has a diameter that is larger than the diameter of the lumen of the cannula body. This aspect may be seen in, for example, Figs. 2A and 2B which are reproduced below.

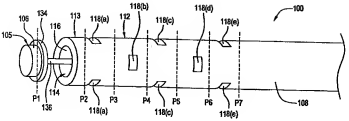

Fig. 2A

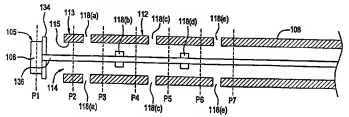

Fig. 2B

Pliable sealing member (134) is illustrated as being disposed on the plunger (106). Paragraph [0034] of the specification describes the claimed aspect of the diameter (in uncompressed state) of the pliable sealing member (134) being larger than the diameter of the lumen (114) of the cannula body (108). By having the diameter be larger, this creates an improved seal between the pliable sealing member (134) and the inner wall of the cannula, thereby ensuring that any openings (whether transverse or longitudinal) located distal to the plunger (106) are no longer in fluid communication with the lumen of the cannula.

Even assuming, *arguendo*, that the injection tube (40) of Margulies et al. can be interpreted as a "sealing member," it is not disposed on a plunger nor does it have a diameter (in an uncompressed state) that is larger than the diameter of the implant (20). In fact, Margulies et al. discloses that the outer dimension of the injection tube (40) "**is slightly smaller than the inner dimension (24) of the hole (23)** . . . ." Col. 4, lines 55-58. Thus, Margulies et al. cannot anticipate claims 48-55 and 66-68 for at least the reason that it does not disclose the aspect of a pliable sealing member that is disposed on a plunger

that also has a diameter this is larger than in the internal diameter of the cannula body (in the uncompressed state).

In addition, Applicants would like to address the comments made in the Office Action regarding the operational details regarding the workings of the Margulies et al. device. The allegation is made that the cement that is initially ejected when the injection tube (40) is fully inserted into the implant (20) would prevent the cement from exiting the longitudinal hole at the distal end of the device. The argument is made that the cement itself forms the seal to prevent cement from exiting the longitudinal hole. Applicants disagree. Margulies et al. describes a method of using a cement material that has "suitable liquidity" such that it **does not harden until after the filling procedure is complete**. This can be seen in the detailed method described in Margulies et al. See Col. 5, lines 23-67 (step (6) – cement hardening comes after the filling procedure is done). Because the cement is in a liquid state during the entire filling procedure, the cement would continue to flow out the distal end of the implant (20). Even when the injection tube (40) is withdrawn proximally and additional cement is extruded (Col. 5, lines 58-61), nothing prevents the "liquid" cement from flowing through the end hole as well as the side holes.

Turning now the rejection of claims 56-60 under § 102(e), Applicant traverses this rejection. In the Office Action, the assertion is made that Margulies et al. discloses a cannula body that includes a plurality of notches (reference is made to Fig. 3a) and that the proximal end of the cannula body is separated from the distal end at one of the plurality of notches. See Office Action, page 4, first ¶. However, this is not what is disclosed in Margulies et al. Rather, Fig. 3a of Margulies et al. discloses a "mechanical weakening" located at (27) between medial and lateral portions of the implant. Col. 4, line 64 – col. 5,

line 2. This mechanical weakening "permits flexure and prevents transferring large bending moments to the lateral femur." Id. The mechanical weakening (27) just provides added flexibility to the implant and is **not** used to separate the implant. Rather, Margulies et al. discloses that the distal, exposed end of the implant (2) is trimmed of excess material. Col. 5, lines 64-67. This trimming does not occur at the point of mechanical weakening (27). For this reason, claims 56-60 are not anticipated by Margulies et al.

§ 103(a) Rejections

Claims 55 and 59 stand rejected under § 103(a) as being unpatentable over Margulies et al. in view of Reiley et al. Claims 55 and 59 are not obvious over the cited prior art because, even assuming that the teachings of Margulies et al. and Reiley et al. were somehow related and combined, the resulting combination would still lack claimed features. For example, with respect to claim 55, neither Margulies et al. nor Reiley et al. disclose or suggest the claimed aspects of the pliable sealing member now found in dependent claim 54. With regard to the rejection of claim 59, as explained above, there is no disclosure contained in Margulies et al. regarding separating the cannula body into proximal and distal portions at one of a plurality of notches. Reilly et al. also does not disclose this feature. Consequently, claims 55 and 59 cannot be rejected as being obvious over Margulies et al. and Reiley et al. because of claimed elements that are neither disclosed nor suggested by the applied prior art references.

Claims 67 and 68 stand rejected under § 103(a) as being unpatentable over Margulies et al. in view of U.S. Patent No. 6,241,734 (Scribner et al.). Contrary to the position taken in the Office Action, Scribner et al. does not disclose a threaded connector

that allows the shortening of the cannula. Rather, Scribner et al. discloses an injection nozzle (106) that connects by a threaded connector (114) to the end of the syringe (104). See FIG. 25 and Col. 10, lines 45-51. The threaded connector is merely used to couple the injection nozzle to the syringe. There is no disclosure in Scribner et al. of a threaded junction located on the cannula body itself (reference (30) in FIG. 25) which is used to separate distal and proximal portions of the cannula. Nor does Scribner et al. disclose or otherwise suggest the claimed feature of claim 68 wherein a distal portion of the cannula body is separated from a proximal portion of the cannula body at a connective sleeve interposed between the distal portion and the proximal portion, the separation effectuated by applying an external removal force to a connective sleeve. Moreover, as explained above, the combination of teachings found in Margulies et al. and Scribner et al. would still fail to disclose or otherwise suggest the claimed feature of the pliable sealing member that is present in base independent claim 66.

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The amendments and remarks presented herein are believed to fully address the outstanding issues set forth in the Office Action and place the claims in condition for

allowance. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (949) 724-1849 (x. 104).

Respectfully submitted,

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Dated: 3/19/2008

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